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# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 4.15

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# QUALITY ASSURANCE FOR RADIOLOGICAL MONITORING PROGRAMS (INCEPTION THROUGH NORMAL OPERATIONS TO LICENSE TERMINATION) — EFFLUENT STREAMS AND THE ENVIRONMENT

## A. INTRODUCTION

This regulatory guide describes a method that the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for use in designing and implementing programs to ensure the quality of the results of measurements of radioactive materials in the effluents from, and environment outside of, facilities that process, use, or store radioactive materials during all phases of the facility's life cycle. QUALITY ASSURANCE[1] (QA) is a fundamental expectation of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) for items and activities that are relied on to protect the health and safety of the public and the environment.

This guide specifically applies to facilities for which NRC regulations require routine monitoring of radioactive effluents to the environment, and particularly those facilities licensed under the following regulations:

- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 1)
- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2)

[1] Special terms used in this guide are marked in SMALL CAPITALS the first time they are used, and are defined in the glossary provided in this regulatory guide.

The U.S. Nuclear Regulatory Commission (NRC) issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff need in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies of this guide and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML071790506.

- 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste" (Ref. 3)
- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste" (Ref. 4)
- 10 CFR Part 76, "Certification of Gaseous Diffusion Plants" (Ref. 5)

The guide also may apply to other facilities licensed by the NRC, for which the agency may impose specific license conditions for effluent or environmental monitoring, as deemed necessary to ensure the health and safety of the public and the environment, including those licensed under the following regulations:

- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" (Ref. 6)
- 10 CFR Part 40, "Domestic Licensing of Source Material" (Ref. 7)
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" (Ref. 8)

Finally, radiological standards for occupational workers and members of the public are codified in 10 CFR Part 20, "Standards for Protection Against Radiation" (Ref. 9).

Although the specific regulations provide the actual requirements, the following presents an overview of applicable NRC regulations addressing limits on radioactive effluents, environmental levels of radioactivity, requirements for effluent and environmental monitoring, and associated QA.

In accordance with 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," the TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) to individual members of the public from licensed operation must not exceed 1 milliSIEVERT [1 mSv, or 100 milliREM (mrem)] per year. Uranium fuel cycle facilities (excluding transportation and disposal) also must comply with the provisions that the U.S. Environmental Protection Agency (EPA) established in 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations" (Ref. 10). In addition, 10 CFR 20.1101(d) requires licensees (other than those subject to 10 CFR 50.34a, "Design Objectives for Equipment to Control Releases of Radioactive Material in Effluents — Nuclear Power Reactors," discussed below) to restrict releases of airborne radioactive materials so that the highest individual dose to the public will not exceed 0.1 mSv (10 mrem) per year.

In addition, under 10 CFR 20.1101(b), licensees must apply AS LOW AS REASONABLY ACHIEVABLE (ALARA) concepts to doses to occupational workers and members of the general public. In accordance with 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public," licensees must survey radiation levels to demonstrate compliance with the dose limits, and 10 CFR 20.1101, "Radiation Protection Programs," requires licensees to develop, document, and implement radiation protection programs commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20 (Ref. 9).

In 10 CFR Part 20, Subpart E, "Radiological Criteria for License Termination," the NRC provides the radiological criteria for license termination under unrestricted and restricted use scenarios. The NRC considers a site acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation does not exceed 25 mrem/year (0.25mSv/year) TEDE to an average member of the critical group, including contributions from groundwater sources. A site can be released under restricted use if the residual radioactivity that is distinguishable from background dose not exceed a yearly dose of 25 mrem (0.25mSv) TEDE with site use restrictions in place.

For nuclear power reactors, 10 CFR 50.34a and 10 CFR 50.36a, "Technical Specifications on Effluents from Nuclear Power Reactors," require ALARA concepts for operations to maintain releases of radioactive materials in effluents consistent with the guidelines of Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50. Licensees must also establish appropriate SURVEILLANCE and monitoring programs to provide QA with respect to (1) areas of equipment operation and (2) data on the quantities or concentrations of radionuclides released in liquid and gaseous effluents. These programs will help to ensure accurate projection of the levels of radiation and radioactive materials found in the environment. Section III.B of Appendix I addresses requirements concerning estimates of radioactive iodine in water and food pathways if land use changes occur after plant construction.

The regulations in 10 CFR 30.34, "Byproduct Material," 10 CFR 40.41, "Source Material," 10 CFR 50.50, "Production and Utilization Facilities," and 10 CFR 70.32, "Special Nuclear Material," provide that the NRC may incorporate in any governed license such terms and conditions as it deems appropriate or necessary to protect health.

For land disposal of radioactive waste, 10 CFR 61.53, "Environmental Monitoring," requires measurements and observations to be made and recorded to provide data to evaluate potential health and environmental impacts, including long-term effects, as well as the need for mitigating measures. The monitoring system must be capable of providing early warning of releases of radionuclides from the disposal site. A postclosure monitoring program is also required to detect the release of radionuclides.

According to 10 CFR 70.59, "Effluent Monitoring Reporting Requirements," licensees authorized to possess and use special nuclear materials for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or in a uranium enrichment facility shall report to the NRC the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents, and other information as the Commission may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases.

Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 includes several applicable general design criteria (GDC) affecting nuclear power plant designs. GDC 60, "Control of Releases of Radioactive Materials to the Environment," requires suitable means to control the release of radioactive materials in gaseous and liquid effluents. GDC 64, "Monitoring Radioactivity Releases," requires means for monitoring effluent discharge paths and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents. GDC 1, "Quality Standards and Records," requires the establishment of a QA program for those structures, systems, and components that are important to safety to provide adequate assurance that they will satisfactorily perform their safety functions. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes the QA requirements for power plants.

The requirements in 10 CFR 72.104, "Criteria for Radioactive Material in Effluent and Direct Radiation from an ISFSI [Independent Spent Fuel Storage Installation] or MRS [Monitored Retrievable Storage]," mandate operational restrictions for maintaining effluents and direct radiation levels in accordance with ALARA concepts, with limits so as not to exceed annual DOSE EQUIVALENTS of .25 mSv (25 mrem) to the whole body, 0.75 mSv (75 mrem) to the thyroid, and 0.25 mSv (25 mrem) to any other critical organ of any real individual beyond the controlled area.

For gaseous diffusion uranium enrichment facilities, 10 CFR 76.87, "Technical Safety Requirements," requires licensees to establish technical safety requirements with procedures and equipment

to address (among other things) building and process ventilation and off-gassing, radioactive waste management, and environmental protection. In addition, 10 CFR 76.93, "Quality Assurance," requires a QA program satisfying the applicable provisions of the American Society of Mechanical Engineers (ASME) standard QA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities (with Addenda)" (Ref. 11).

Generic Letter 79065 (Ref. 12), regarding the NRC's Radiological Assessment Branch Technical Position on Radiological Environmental Monitoring, provides guidance on the appropriate type of, and location for, sampling and monitoring the environment surrounding nuclear power plants.

This regulatory guide presents more complete and extensive guidance on QA for facilities where radiological effluent or environmental monitoring is required by NRC regulations.[2] However, this guidance does not address all topics and elements that a facility's QA program may require (such as requirements of Appendix B to 10 CFR Part 50 for nuclear power plants or 10 CFR 76.93 for gaseous diffusion uranium enrichment facilities).

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required.

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[2] While not specific to QA, other regulatory guides that address measurements of radioactive materials in effluents and the environment include the following:

- Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Materials in Liquid and Gaseous Effluents from Light-Water-Cooled Nuclear Power Plants" (Ref. 13)
- Regulatory Guide 4.1, "Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants" (Ref. 14)
- Regulatory Guide 4.14, "Radiological Effluent and Environmental Monitoring at Uranium Mills" (Ref. 15)
- Regulatory Guide 4.16, "Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants" (Ref. 16)

# B. DISCUSSION

As used in the context of this guide, QA comprises all those planned and systematic actions that are necessary to provide adequate confidence in the ASSESSMENT of monitoring results. QUALITY CONTROL (QC) comprises those QA actions that provide a means to measure and control the characteristics of measurement equipment and processes to meet established standards; QA includes QC. This guide makes no further effort to distinguish those elements that may be considered QC from those composing QA.

Quality assurance is necessary to ensure that all radiological and nonradiological measurements that support the radiological monitoring program are reasonably valid and of a defined quality. These programs are needed (1) to identify deficiencies in the sampling and measurement processes and report them to those responsible for these operations so that licensees may take CORRECTIVE ACTION and (2) to obtain some measure of confidence in the results of the monitoring programs to assure the regulatory agencies and the public that the results are valid. All steps of the monitoring process should involve QA (e.g., sampling, shipment of SAMPLES, receipt of samples in the laboratory, preparation of samples, radiological measurements, data reduction, data evaluation, and reporting of the measurement and monitoring results) .

An effective overall management system for quality must precede the design of a QA program. A document by the International Organization for Standardization (ISO/IEC 17025-2005, Ref. 17) is available for use by laboratories in developing their management system for quality, administrative, and technical operations. Once a quality management system is in place, a DIRECTED PLANNING PROCESS can be used to define the data objectives for the specific monitoring program. The DATA QUALITY OBJECTIVE (DQO) process (EPA QA/G-4-2006, Ref. 18) provides one example of how to develop and define acceptance and performance criteria for a sample collection, measurement, and data analysis program. The QUALITY ASSURANCE PROJECT PLAN (QAPP), which documents how data will be collected, assessed, and analyzed, can form the basis of a QA program (EPA QA/G-5-2002, Ref. 19). The QAPP provides a blueprint of where, when, why, and how a particular project will achieve data of the type and quality needed and expected.

NUREG-1576, "Multi-Agency Radiological Laboratory Analytical Protocols Manual" (Ref. 20, hereafter referred to as MARLAP), contains guidance for developing DQOs for risk-informed decisions, and their consequent MEASUREMENT QUALITY OBJECTIVES (MQOs), in the context of radiochemical analyses of environmental samples. The same methodology can be applied in other environmental monitoring contexts. An example of a key MQO is the REQUIRED METHOD UNCERTAINTY at a specified radiation dose or radionuclide concentration. The specific dose may be a fractional amount of a radiation dose limit. The specific concentration may be a fractional amount of an effluent release or environmental radionuclide concentration. For either case, the fractional amount of the limit should be sufficiently small so that a licensee may take reasonable operational actions before the limit is exceeded. MARLAP recommends a PERFORMANCE-BASED APPROACH for selecting methods used to analyze samples or measure dose rates that meet the MQOs. Under this approach, the licensee's QA program should incorporate the initial (project METHOD VALIDATION) and continued [internal and external PERFORMANCE EVALUATION (PE) PROGRAMS] assessment of a method's capability to meet the MQO specifications. Process-radiation monitoring equipment and instrumentation need to have the desired sensitivity to provide both real-time and data-trend values that can correlate to the actual measurements of process streams before release. The radiological environmental measurements program may be used to confirm the adequacy of the process-monitoring equipment.

# C. REGULATORY POSITION

The QA program of each organization performing radiological effluent or environmental monitoring of nuclear facilities using, processing, or storing radioactive materials during all phases of the facility's life cycle should be documented by written policies and procedures. Licensees should have sufficient RECORDS of program conduct and performance to demonstrate program adherence. In addition to its own program, a licensee should require any contractor or subcontractor performing support program activities (e.g., sampling, analysis, evaluations, and records) retain records sufficient for the licensee to develop and maintain a QA program covering the applicable program elements.

The following presents the QA program elements that should be developed and implemented to ensure the quality of data/results for radiological effluent and environmental monitoring programs.

## 1. Organizational Structure and Responsibilities of Managerial and Operational Personnel

The structure of the organization as it relates to the management and operation of the monitoring programs, including QA policy and functions, should be defined and documented. The authorities, duties, and responsibilities of the positions within this organization, down to the first-line supervisory level, should be described. This should include responsibilities for review and approval of written procedures and the preparation, review, and evaluation of monitoring data and reports.

Persons and organizations performing QA functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Reporting should be at a management level that is independent of activity performance, costs, and schedule.

Section 2.1.1 of ANSI/ASQC E4-1994 (Ref. 21) and Section 5.2.1 of ANSI N42.23-2003 (Ref. 22) provide additional guidance on management structure and organizational responsibilities for radiological effluent and environmental monitoring programs.

## 2. Specification of Qualifications of Personnel

The qualifications of individuals needed to carry out assigned radiological monitoring functions should be defined and documented (e.g., as in a job description). Individuals with responsibility for performing quality-related activities should be trained and qualified in the principles and techniques of the activities to be performed. These individuals should maintain proficiency by retraining, reexamining, and recertifying or by periodic performance reviews, as appropriate. Continual training should be conducted as needed to ensure that personnel maintain awareness of events and issues that could affect the quality of program performance.

Section 2.3.1 of ANSI/ASQC E4-1994 (Ref. 21) provides additional guidance and criteria for developing personnel training and qualification specifications for radiological effluent and environmental monitoring programs.

## 3. Operating Procedures and Instructions

Monitoring programs should have written procedures for all activities that generate data, such as dose calculations and measurements, sample collection, sample management and CHAIN OF CUSTODY, sample preparation and analysis, data reduction and recording, data assessment and reporting, and final sample disposal. Procedures are also needed for addressing support functions, such as operation of process monitors, training, preparation of QUALITY CONTROL SAMPLES, collection of meteorological data, corrective actions, AUDITS, and records. Individuals satisfying the qualifications described in Section C.2 of this regulatory guide should write, review, and revise these procedures.

Instructions, procedures, or schedules should be prepared for the functions associated with the QA program, such as the following:

- ancillary laboratory functions (including cleaning of glassware, contamination control, and storage of standards and chemicals)
- CALIBRATION and QC of instrumentation (including range of activity, range of energy, and frequency of calibration)
- internal QC and external PE programs (including frequency, types, acceptance criteria for the laboratory PERFORMANCE TESTING samples, and individual analyst qualifications)
- timetable for VERIFICATION and VALIDATION (V&V) of data

Chapters 9, 11, and 12 of MARLAP (Ref. 20) provide guidance on the radioanalytical laboratory activities for which procedures are used. MARLAP Chapters 12 – 16 provide technical information that can be used to write or revise procedures. Section 5.4 of ISO/IEC 17025-2005 (Ref. 17) provides additional guidance regarding the content and quality aspects of procedure and method technical content. Section 2.5.2 of ANSI/ASQC E4-1994 (Ref. 21) identifies procedures that should be documented and may need control.

## 4. Records

licensees should maintain a system that produces unequivocal, accurate records that document all monitoring activities. Licensees should maintain records of implementation or ongoing activities, such as the following:

- procedure revision
- personnel training and qualification records
- analytical results
- audits
- corrective actions
- intermediate activities or calculations (as may be needed to validate or substantiate final results)
- records of tracking and control (chain of custody) throughout all processes from sample collection through analysis and reporting of results, including unique identifiers, descriptions, sources, dates/times, packaging/preparation/shipping, and required analyses
- field logs with sufficient information describing environmental conditions and recording related information and data documenting the nature of the sample and where and how it was taken
- laboratory notebooks recording related information and data, observations of analysts, and laboratory or other conditions potentially affecting the measurement process
- electronic data collection and algorithms and QA documentation
- calculations (including data reduction, analysis, and verification)

- QC records for radiation monitoring equipment, including the results of RADIOACTIVE SOURCE checks, calibrations, INSTRUMENT BACKGROUND determinations, and maintenance activities affecting equipment performance
- notifications to qualified staff that procedural changes affecting data quality have been made
- QC records for laboratory counting systems and support instrumentation and equipment, including calibrations, maintenance or repair, QC sample results, and traceability of standards used for instrument calibration

Records should be legible and identifiable, retained in predetermined locations, and protected against damage, deterioration, or loss. Records should be maintained in a format that is easily retrievable. If the media for storage is electronic (as opposed to paper or microfilm/fiche), the licensee should maintain the equipment necessary to read and present the data in an uncorrupted form. The document retention system should allow reconstruction of all activities associated with the generation of analytical results. The licensee should establish a retention time for records consistent with licensing conditions and in accordance with the licensee's overall QA program.

Section 2.5 of ANSI/ASQC E4-1994 (Ref. 21) provides guidance on specific types of documents that should be maintained, while Basic Requirement 17 of ASME NQA-1-1994 (Ref. 11) details the administrative criteria that should be considered for inclusion in a program for records and their retention. Section 4.13 of ISO/IEC 17025-2005 (Ref. 17) also provides guidance on the control of records. Chapters 4 and 11 of MARLAP (Ref. 20) discuss documents that should be retained as records. Nuclear Information and Records Management Association (NIRMA) TG11-1998 (Ref. 23), TG15-1998 (Ref. 24), TG16-1998 (Ref. 25), and TG21-1998 (Ref. 26) provide additional information addressing issues in developing and maintaining electronic records programs.

## 5. Quality Control in Environmental Sampling

Sampling of solids, liquids, and gases involves the measurement of sample masses, flow rates, or volumes. The ACCURACY of the instruments or containers used for this purpose should be determined and checked regularly to ensure that sampling performance criteria remain within the limits specified by the MQOs. The results of mass, flow rate, or volume calibrations and associated UNCERTAINTIES should be recorded. The frequency of these calibrations should be specified and should be consistent with the DQOs of the measurement program. The collection efficiencies of the sampling equipment used should be documented; often such documentation is available from the manufacturer. HPS/ANSI N13.1-1999 (Ref. 27) provides guidance on QA and QC for air sampling instruments. Chapter 19 of MARLAP (Ref. 20) discusses measurement uncertainties in general and volume and mass measurements in particular.

Sampling or measurements should be performed using equipment and methods that yield a result that is representative of the population in the particular environmental media. FIELD DUPLICATES are co-located spatially or temporally and should be collected periodically to check REPRODUCIBILITY. Chapter 10 of MARLAP (Ref. 20) discusses the field and sampling issues that affect laboratory measurements, including packaging, shipping, and storage of samples.

Some individual environmental samples are collected simply to confirm that radioactivity levels are below a specified (small) fraction of an established concentration limit. In those cases, the MINIMUM DETECTABLE CONCENTRATION of the method used should be below that specified fraction of the limit. Chapter 20 of MARLAP (Ref. 20) discusses detection limits, while Appendix C to MARLAP covers the relationship between the desired fraction of the limit that is important to detect and the uncertainty of the measurement method. In some cases, a series of measurement results will be averaged for comparison with BACKGROUND LEVELS or a regulatory limit. For such measurements, an appropriate MQO would be the MINIMUM QUANTIFIABLE CONCENTRATION (see Chapter 20 of MARLAP).

For an isolated, well-mixed population, a single sample or measurement may be sufficient. It is more common, however, for spatial or temporal variations to exist. In that case, the frequency of sampling and number of samples and locations will depend on the level of variability and amount of radioactivity (compared with an established risk-informed limit). NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (Ref. 28, hereafter referred to as MARSSIM), discusses the effect that such variability has on the number of samples that may be appropriate for SURVEYS. In general, the DQO process may be used together with specific statistical designs (EPA QA/G-9S-2006, Ref. 29) to optimize the sampling. Continuous sampling or integrated measurements may be used to mitigate temporal variability.

Part 1, Sections II-11 and II-12, of ASME NQA-1-1994 (Ref. 11) discuss test control and control of measuring and test equipment. Part II, Subpart 2.20, of ASME NQA-1-1994 discusses QA standards for subsurface investigations for nuclear power plants.

## 6. Quality Control in the Radioanalytical Laboratory

The output of the directed planning process includes DQOs that encompass both sampling and analysis activities for a project or program. From the DQOs, a set of MQOs are developed for radioanalytical measurements (see Chapter 3 of MARLAP, Ref. 20). In a performance-based approach, MQOs are critical criteria used for the selection and validation of analytical methods and protocols (see Regulatory Position 8, below) and subsequently form the basis for the ongoing and final evaluation of the analytical data. The type, frequency of, and evaluation criteria for QC samples are developed during the directed planning process and are incorporated into ANALYTICAL PROTOCOL SPECIFICATIONS (APSs) for a project (see Chapter 3 of MARLAP, Ref. 20).

Chapter 18 of MARLAP provides guidance on monitoring key laboratory PERFORMANCE INDICATORS to determine whether a laboratory's measurement processes are in control. The chapter also provides information on likely causes of excursions for selected laboratory performance indicators, such as chemical yield, instrument background, and QC samples. Appendix C to MARLAP provides the rationale and guidance for developing MQOs for select method performance characteristics and gives guidance on developing criteria for QC samples.

Performance criteria for radioanalytical measurements should be selected to provide a management tool for tracking and trending performance and to identify precursors to nonconforming conditions. Laboratories should satisfy program-specific criteria for all measurement processes, including necessary levels of PRECISION, acceptable BIAS, and applicable detection levels.

### 6.1 Calibration and Quality Control of Instruments, Measuring Devices, and Test Equipment

Instruments, devices, and test equipment used for measuring radioactivity should be operated, calibrated, and maintained to ensure that analytical specifications are met. All equipment should be operated, calibrated, and maintained in adherence to any applicable standards and methods and as specified in the laboratory's quality manual and standard operating procedures. Instrument configurations during calibration should match those used for subsequent analytical measurements of samples.

Calibrations of instruments should be made using CERTIFIED REFERENCE MATERIALS of known and documented value and stated uncertainty and should be traceable to a national standards body, such as the National Institute of Standards and Technology (NIST) in the United States. CALIBRATION SOURCES should be prepared in a manner that provides comparability to TEST SOURCES with respect to source geometry, positioning relative to the detector, source composition, and distribution of the test-source material within a container or on a source mount (see Section 15.2 of MARLAP, Ref. 20).

The frequency of calibrations should be consistent with the stability and performance of the instrument. Complete system calibration should be performed before initial use or following system maintenance, repair, or any other changes in environment or operating conditions that could affect performance (ASTM D7282-2006, Ref. 30). In addition, Sections 15.2 and 15.3 of MARLAP (Ref. 20) present general guidance regarding calibrations of instruments. Chapter 15 of MARLAP also presents guidance specific to calibrations of different instrumentation types.

The continuing validity of calibrations should be checked periodically as specified in a laboratory's quality manual (see Chapter 18 of MARLAP, Ref. 20). Quality control checks of radioanalytical instrument calibration parameters, such as detector response or energy and resolution calibrations for spectrometers, should be performed by measuring the response of each radiation detection system to appropriate CHECK SOURCES. Instrument QC frequencies are generally performed daily for systems used continually or before use for those systems periodically employed, but frequencies may vary by instrument type. Instrument QC checks should meet predefined acceptance criteria for the respective calibration parameter and should ensure that conditions have not significantly changed since initial calibration (ASTM D7282-2006, Ref. 30).

Instrument-calibration QC check results should be tracked, trended, and compared with predetermined ranges of acceptable performance. For example, if a monitor's response to a daily check source showed a trend that may lead to a condition outside of established acceptance criteria, a calibration may be needed to reestablish acceptable operation. Section 18.5 of MARLAP (Ref. 20) and ASTM D7282-2006 (Ref. 30) discuss radioanalytical instrument-calibration QC parameters.

Additional method-specific quality controls (e.g., chemical yield, spectral quality, resolution) may apply to certain methods and should be tracked and trended using control or tolerance charts to identify conditions that could be adverse to quality.

The laboratory quality manual and standard operating procedures should address the use, calibration, maintenance, and QC of all nonradiological instruments, measuring devices, and test equipment used for measuring or quantifying other necessary data (e.g., sample masses or volumes, temperatures). All measurement and test equipment should be calibrated before use and adjusted to maintain accuracy within established limits. Quality control checks should be performed at specified frequencies and should verify that instruments are operating to specified performance levels.

Nonradiological instruments, measurement, and test equipment should be operated according to manufacturers' instructions, according to established standards, or as specified in the laboratory quality manual and procedures. Section 18.6.7 of MARLAP (Ref. 20) provides guidance on control, calibration, and maintenance of calibration of apparatus used for mass and volume measurements. ISO/IEC 17025-2005 (Ref. 17) provides general guidance on establishing quality controls for nonradiological instruments. Items that do not conform to specified criteria should be controlled to prevent inadvertent use. These items should be tracked through the corrective action program.

Careful control of contamination and routine monitoring of instrument background are integral parts of a measurement QC program. Determination of the background counting rate should be performed on a regular, predefined frequency for systems in routine use and should ensure that analytical specifications for applicable programs can be met. Instrument backgrounds used to determine a net count rate should replicate actual sample measurement conditions as closely as possible (i.e., using appropriate sample containers and geometries).

Section 18.5.1 of MARLAP (Ref. 20) provides guidance on measurement and control of instrument backgrounds. Section 18.3 and Attachment 18A of MARLAP contain guidance on the statistical evaluation of performance indicators and on using control and tolerance charts.

Sections 10-13 and 20-25 of ASTM D7282-2006 (Ref. 30) and Section A.5.2 of ANSI N42.23-2003 (Ref. 22) provide additional guidance on instrument response source checks, background checks, and the use of control charts. ASTM MNL 7A-2002 (Ref. 31) provides guidance on setting up and using control charts.

## 6.2 Internal Quality Control Samples and Analysis

The use of QC samples should be an integral element of a laboratory QA program. Chapter 18 of MARLAP (Ref. 20) defines the different types of laboratory QC samples and provides guidance on evaluation techniques for QC samples. The laboratory should have as part of the normal operational sample load the following QC samples:[3]

- BLANK
- MATRIX SPIKE
- LABORATORY CONTROL SAMPLE
- LABORATORY DUPLICATE

Analysis of QC samples should be performed as a part of the routine operation of a laboratory to verify that laboratory operations are consistent with applicable specifications. The QC program should specify the type of and minimum frequency for processing QC samples. For example, this frequency may be defined as a minimum percentage of the total number of samples analyzed, a certain number per operational time interval (e.g., once per shift) or per sample batch, or a licensee-specified frequency based on laboratory-specific parameters. As part of its QC program, the laboratory may prepare and analyze BLIND SAMPLES, provided the individuals responsible for preparing the samples are not directly responsible for conducting the laboratory analysis. For example, the laboratory's assigned QC specialist may have the responsibility for preparing and submitting blind samples (blank, duplicate, laboratory control sample, and matrix spike). Blind samples are used primarily as a tool for evaluating the performance of individuals rather than as part of the laboratory QC load.

Acceptability of QC sample results should be evaluated based on criteria from the QC program, which include specific equations based on METHOD UNCERTAINTY. Chapters 7 and 18 of MARLAP (Ref. 20) provide guidance on the evaluation of QC samples.

Quality control sample results should be tracked, trended, and compared with predetermined ranges of acceptable performance to identify conditions that are in, or may lead to, nonconformance with program specifications. Such conditions should be tracked through the corrective action program.

## 6.3 Performance Evaluation Program (Interlaboratory Comparison)

Participation in an external PE program is an important independent check on the accuracy, possible bias, and precision of some radioanalytical or measurement methods used in a radiological monitoring program. Internal and contract radioanalytical laboratories used in the monitoring program should participate in one or more applicable PE programs that are administered by organizations that have an active measurement assurance (traceability) program with NIST (ANSI N42.22-1995, Ref. 32). Chapter

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[3] Note that this list does not include field duplicate samples that are part of the QC requirement for sampling.

5 of MARLAP (Ref. 20) recommends incorporating the criteria for a radioanalytical laboratory to participate in a PE program into the statement of work for services. Several external PE programs administered by government agencies or commercial radioactive-source suppliers are available for radionuclides and matrices germane to radiological monitoring programs. The PE program should provide fundamental sample types (e.g., solid, liquid, gas) and radionuclides (e.g., alpha-, beta-, and gamma-emitting nuclides) of interest at the facility. When available, laboratories should analyze samples as offered by a PE program on a frequency stipulated by the monitoring program's QA criteria, with all types of samples and analyses repeated at least biennially. Chapter 18 of MARLAP (Ref. 20) provides information on organizations that administer PE programs.

Acceptable performance criteria for results of performance-testing samples should be established that are consistent with the MQOs for the radiological monitoring project or program. For certain monitoring activities, the acceptance criteria of the PE program may be satisfactory. The performance in a PE program should be tracked and trended as one of the performance indicators for the laboratory and evaluated as part of the corrective action program.

## 7. Quality Control for Radioactive Effluent Monitoring Systems

### 7.1 Radioactive Effluent Process Monitors

An initial, primary radiation monitor calibration that meets the specifications of ANSI N42.18-2004 (Ref. 33), should be performed with radioactive sources traceable to a national standards body (such as NIST). Calibrations should be repeated periodically using (1) STANDARD REFERENCE MATERIALS or (2) certified reference materials that can be directly traced to the initial, primary calibration. Complete system calibration — including electronics, detector, and any support functions (such as alarm, display, and recording devices) — should be performed at a frequency that ensures system reliability and accuracy or after repair or maintenance that may affect instrument calibration. Unless otherwise specified in license requirements, the licensee should verify and validate the complete effluent monitoring system every 12 months. This frequency may be extended to longer time periods coinciding with facility maintenance schedules, such as refueling for nuclear power plants, if the licensee has verified proper system operation through established system reliability and more frequent source checks and functional checks.

Detectors should be response-checked periodically[4] for continuous effluent release points (e.g., ventilation systems and secondary water systems) and before release for batch discharges (e.g., primary boundary or containment purges and liquid waste tank releases). Licensees should ensure that check sources are of sufficient radiochemical purity so that the activity of the source may be corrected for decay to the date of measurement. These check sources need not be traceable to a national standards body (e.g., NIST). Whenever practicable, check sources should be an integral part of the monitoring system and should be remotely actuated. The functionality of isolation or alarm functions should be verified periodically, preferably by use of a radiation source.

Trends of process radiation monitor readings versus total radionuclide concentrations in the monitored release path should be performed routinely. These trends should be based on the results of analyses for specific radionuclides in samples taken from the release path that will yield a monitor response. Deviations in the trend may occur if concentrations or the mixture of radionuclides changed significantly (for example, during a fuel cycle in which significant fuel defects exist). The licensee should define the monitor-response parameter for all radiation monitors. The monitor-response constant should be adjusted to maintain this correlation between effluent radionuclide concentration and monitor response.

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[4] Frequencies should be appropriate to the instrument under consideration and may be dictated by license conditions.

## 7.2 Flow Monitoring Instrumentation

Continuous sampling of liquids and gases involves the measurement of sample flow rates and/or sample volumes. The accuracy and associated uncertainty of the devices used for this purpose should be determined on a regularly scheduled basis, and adjustments should be made as needed to bring the performance of the devices within specified limits. The results of these calibrations should be recorded. The frequency of these calibrations should be specified and should be based on the necessary accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Any flow-rate measuring devices associated with the system should be calibrated to determine actual flow rates at the conditions of temperature and pressure under which the system will operate. These flow rate devices should be recalibrated annually, but the frequency may be extended to that established for the radiation detector system, provided sufficient operating experience exists and an accelerated measurement check frequency gives sufficient data to ensure reliable performance.

Flow measuring devices should be checked periodically on an established frequency, considering the variability of the instrument, and recalibrated when established control limits are exceeded. HPS/ANSI N13.1-1999 (Ref. 27) provides additional guidance on QA and QC measures for the use, maintenance, and calibration of airborne sampling instrumentation. ANSI N42.18-2004 (Ref. 33) provides additional guidance on the calibration of liquid flow monitors.

## 7.3 Grab Sampling of Effluent Process Streams

Whenever practicable, effluent releases should be batch-controlled and released when the volume to be released has been mixed sufficiently to ensure uniform concentration. Sampling and analysis for each batch should be performed, and release conditions set, before release. A certain percentage of all batch releases should have field duplicates taken either before or during the release to assess the reproducibility of sampling and the effectiveness of the mixing process before release. Where possible, samples that are spatially or temporally separated should be collected periodically to verify representativeness.

For continuous-effluent discharges, composite samplers should be employed. However, periodic grab samples may be used when composite sampling of a continuous discharge point is not feasible. When grab samples are collected instead of composite samples, licensees should design the sampling program to sample at the time, location, and frequency that ensures each sample is representative of the radioactive materials released.

## 7.4 General Quality Control Considerations

The QC plan should address the following items:

- Sampling should be performed using calibrated instruments and equipment when taking a composite sample.
- Collection efficiencies based on the physical configuration of the sampling point and the type of collector should be documented. Vendor-supplied data may be used where adequate documentation exists to ensure the reliability and accuracy of data.
- Volumes of tanks and containers should be established during initial installation and should be verified again following any physical changes that could alter the system configuration.

- The frequency of duplicates and REPLICATES[5] should be established based on time (for continuous discharges) or number of batches (for batch discharges).
- Sample integrity should be maintained through chain of custody procedures.

Procedures for continuous sampling should use methods that are designed to ensure that the sample is representative of the volumes being discharged.

## 8. Verification and Validation

The V&V of certain aspects and support activities of the radiological measurement process or monitoring program are essential to the QA program. These aspects and activities include data and computer software V&V and project method validation.

Project method validation is the demonstration that a method (radioanalytical or radiation measurement) using performance-based method selection is capable of providing analytical results to meet a project's MQOs and any other criteria in the analytical protocol specification (APS). Acceptable method validation is necessary before the radiological analysis of samples or the taking of measurements in a monitoring program. Chapter 6 of MARLAP (Ref. 20) presents detailed guidance on project method validation for radioanalytical methods. In addition, Section 5.2.7 of ANSI N42.23-2003 (Ref. 22) and Section 5.4.5 of ISO/IEC 17025-2005 (Ref. 17) provide limited guidance for radioanalytical method validation.

Chapter 8 of MARLAP (Ref. 20) gives detailed guidance and applicable tools for the radioanalytical data V&V evaluation process as well as information for developing a data V&V plan, determining acceptable criteria and tests, and applying data qualifiers for radioanalytical data validation, as related to MQOs. EPA QA/G-8-2002 (Ref. 34) provides guidance for nonradioanalytical data V&V.

Computer programs used in the implementation of the radiological environmental monitoring program should be documented, verified, and validated before initial routine use and after each modification of the program. As described in Section 5.4.3.2 of MARLAP (Ref. 20), the laboratory's quality manual should include the criteria for computer software V&V and documentation. The software data reduction and reporting functions should be verified to perform as expected.[6]

## 9. Assessments and Audits

Assessments, audits, and surveillances are elements used to evaluate the initial and ongoing effectiveness of the QA program to monitor and control the quality of a radiological monitoring program. Management having responsibility in the area being reviewed should document and review the results of these activities. Assessments that are independent of the day-to-day operations should be performed routinely, including management surveillance, peer reviews, and READINESS REVIEWS for new or revised systems and methods. Key performance indicators should be tracked and trended, with periodic management reporting. The QA program or project plan should outline the scope, frequency, and schedule of assessments, audits, and surveillances. A plan should be developed for each assessment audit or

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[5] Replicate samples may be prepared by removing separate ALIQUANTS from the same grab sample.

[6] The Institute of Electrical and Electronics Engineers (IEEE) Standard 1063, "IEEE Standard for Software User Documentation" (Ref. 35); EPA Directive 2185, "Good Automated Laboratory Practices" (Ref. 36); Subpart 2.7 of ASME NQA-1-1994 (Ref. 11); Regulatory Guide 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Used Safety Systems of Nuclear Power Plants" (Ref. 37); and Section 8 of ANSI N42.14-1999, "Calibration and Use of Germanium Spectrometers for the Measurement of Gamma-Ray Emission Rates of Radionuclides" (Ref. 38), also provide guidelines on software V&V.

surveillance for each area of the monitoring program being evaluated. A report of these activities should be generated according to the outline, format, and content established in the plan.

Only qualified QA staff (see Regulatory Position 2, above), supported as needed by experts in the technical areas under evaluation, should conduct assessments, audits, and surveillances. (See ASME NQA-1-1994, Supplement 2S, Ref. 11.) Deficiencies, areas for improvement, and observations noted should be incorporated into the corrective action program and tracked. Section 18 of ASME NQA-1-1994 (Ref. 11) and Section 4.10 of ISO/IEC 17025-2005 (Ref. 17) provide guidance on establishing and conducting an audit program.

When the monitoring program will depend upon the services of a radioanalytical laboratory, prior onsite audits of the laboratory may be conducted to ensure that the laboratory is capable of fulfilling the project criteria in accordance with the APS (including MQOs) outlined in a statement of work (MARLAP Chapter 5 and Appendix E). The ongoing evaluation of the laboratory's QUALITY SYSTEM and operations is accomplished through onsite audits and desk audits. These audits are focused more on whether the laboratory is meeting project or program specifications than whether the laboratory has the capability to meet monitoring program or project criteria. Chapter 7 of MARLAP provides guidance and statistical tests to determine whether a laboratory is meeting the MQOs, especially the REQUIRED METHOD UNCERTAINTY. Section 5.2.10 of ANSI N42.23-2003 provides additional guidance for radioanalytical laboratory assessments.

Audits of the QA programs of contractors providing materials, supplies, or services affecting the quality of the laboratory's operations should be performed periodically (Section 4.6 of ISO/IEC 17025-2005, Ref. 17).

## 10. Preventive and Corrective Actions

Integral components of a QA program include identifying areas for improvement, defining performance or programmatic deficiencies, and initiating appropriate corrective or preventive actions. The QA program for radiological effluent and environmental monitoring programs should contain both a continuous-improvement program and a program for implementing corrective actions when conditions adverse to quality have been identified. In addition, needed improvements and potential sources of nonconformance should be identified and reported as part of a preventive action initiative of the continuous-improvement program (ISO/IEC 17025-2005, Sections 4.10–4.12) — for example, a condition-reporting program. Investigations should be initiated for degrading conditions, and corrective actions should be taken when conditions fall outside quality or regulatory acceptance criteria. For conditions that are adverse to quality, the corrective action process includes the following basic elements:

- identification and documentation
- classification
- cause analysis
- corrections
- followup
- closure

Findings and corrective actions should be documented, tracked, and reported to management. Followup reviews should be performed to verify the effectiveness and adequacy of the corrective actions. Section 2.10 of ANSI/ASQC E4-1994 (Ref. 21) provides specifications and guidelines for developing the process, programs, and procedures necessary to detect and correct items of nonconformance and for implementing continuous quality improvement.

When conducting an audit or surveillance of laboratory services, a prime area of review should be the effectiveness of the laboratory's corrective action program (Section 7.4.2 of MARLAP, Ref. 20). Section 4.11 of ISO/IEC 17025-2005 (Ref. 17) provides general guidance on preventive and corrective action programs for laboratories. Annex C of ANSI N42.23-2003 (Ref. 22) provides additional guidance that should be considered in developing a corrective action program, including root cause analysis for radioanalytical services.

# D. IMPLEMENTATION

The purpose of this section is to provide information to licensees regarding the NRC staff's plans for using this regulatory guide. No backfit is intended or approved in connection with its issuance.

Non-nuclear power reactor applicants and licensees may continue to use Revision 1 of Regulatory Guide 4.15, dated February 1979, or may adopt other procedures or practices that reflect generally accepted standards for ensuring quality in environmental data collected for effluent monitoring purposes. Except in those cases in which a nuclear power reactor applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods and practices described in this guide will be used in evaluating QA practices for environmental radiological monitoring programs.

# GLOSSARY[7]

**accuracy**—The closeness of a measured result to the true value of the quantity being measured. Various recognized authorities have given the word "accuracy" different technical definitions, expressed in terms of bias and imprecision. Following the Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) Manual (Ref. 20), the U.S. Nuclear Regulatory Commission (NRC) avoids all of these technical definitions and uses the term "accuracy" in its common, ordinary sense, which is consistent with the definition established by the International Organization for Standardization (ISO) in the "International Vocabulary of Basic and General Terms in Metrology" (Ref. 39).

**aliquant**—A representative portion of a homogeneous SAMPLE removed for the purpose of analysis or other chemical treatment. The quantity removed is not an evenly divisible part of the whole sample. An aliquot, by contrast, is an evenly divisible part of the whole.

**analyte**—See TARGET ANALYTE.

**analytical protocol specification (APS)**—The output of a DIRECTED PLANNING PROCESS that contains the project's analytical data needs and criteria in an organized, concise form. The level of specificity in the APS should be limited to those criteria that are considered essential to meeting the project's analytical data criteria to allow the laboratory the flexibility of selecting the protocols or methods that meet the analytical criteria.

**as low as reasonably achievable (ALARA)**—"As low as is reasonably achievable taking into account the state of the technology and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest" [10 CFR 50.34a(a)].

**assessment**—A planned and documented activity performed to determine whether various elements within a quality management system are effective in achieving stated quality objectives (ANSI N42.23-2003, Ref. 22).

**audit**—A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of, and CONFORMANCE with, established procedures, instructions, drawings, and other applicable documents as well as the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance (after ANSI N42.23-2003, Ref. 22).

**background, instrument**—Radiation detected by an instrument when no SOURCE is present. The background radiation that is detected may come from radionuclides in the materials of construction of the detector, its housing, its electronics, and the building as well as the environment and natural radiation.

**background level**—A term that usually refers to the presence of radioactivity or radiation in the environment. From an analytical perspective, the presence of background radioactivity in samples

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[7] Certain terms included in this glossary are not used in the main body of this regulatory guide, but are included because they are used within other definitions.

needs to be considered when clarifying the radioanalytical aspects of the decision or study question. Many radionuclides are present in measurable quantities in the environment.

**bias (of a measurement process)**—A persistent deviation of the mean measured result from the true or accepted reference value of the quantity being measured, which does not vary if a measurement is repeated.

**blank (analytical or method)**—A SAMPLE that is assumed to be essentially free of the TARGET ANALYTE (the "unknown"), that is carried through the radiochemical preparation, analysis, mounting, and measurement process in the same manner as a routine sample of a given matrix.

**blind sample**—A SAMPLE with a concentration not known to the analyst. Blind samples are used to assess analytical performance. A double-blind sample is a sample whose concentration and identity as a sample is known to the submitter, but not to the analyst. The analyst should treat the double-blind sample as a routine sample, so it is important that the double-blind sample is identical in appearance to routine samples.

**calibration**—The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known value of a parameter of interest.

**calibration source**—A prepared SOURCE, made from a CERTIFIED REFERENCE MATERIAL OR STANDARD REFERENCE MATERIAL, that is used for calibrating instruments.

**certified reference material**—A reference material, accompanied by a certificate, with one or more property values certified by a procedure that establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an UNCERTAINTY at a stated level of confidence (ISO Guide 30, Ref. 40). See STANDARD REFERENCE MATERIAL.

**chain of custody**—Procedures that provide the means to trace the possession and handling of a sample from collection to data reporting.

**check source**—A material used to validate the operability of a radiation measurement device, sometimes used for instrument quality control. See TEST SOURCE and SOURCE, RADIOACTIVE.

**condition adverse to quality**— an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

**conformance**—An affirmative indication or judgment that a product or service has met the criteria of the relevant specifications, contract, or regulation; also the state of meeting the criteria (ANSI/ASQC E4-1994, Ref. 21).

**corrective actions**—Those measures taken to prevent, rectify, or eliminate conditions adverse to quality or detected nonconformities and — as necessary — to preclude repetition of those conditions.

**data quality objective (DQO)**—Qualitative and quantitative statements that clarify the study objectives, define the most appropriate type of data to collect, determine the most appropriate conditions from which to collect the data, and specify tolerable limits on decision error rates. Because DQOs will be used to establish the quality and quantity of data needed to support decisions, they should

encompass the total UNCERTAINTY resulting from all data collection activities, including analytical and sampling activities.

**directed planning process**—A systematic framework focused on defining the data needed to support an informed decision for a specific project. Directed planning provides a logic for setting well-defined, achievable objectives and developing a cost-effective, technically sound sampling and analysis design that balances the data user's tolerance for UNCERTAINTY in the decision process and the available resources for obtaining data to support a decision. Directed planning helps to eliminate unnecessary, poor, or inadequate sampling and analysis designs.

**dose equivalent**—Quantity that expresses all radiations on a common scale for calculating the effective absorbed dose. This quantity is the product of absorbed dose (GRAYS (Gy) or rads) multiplied by a quality factor and any other modifying factors (MARSSIM, Ref. 28). The quality factor adjusts the absorbed dose because not all types of ionizing radiation create the same effect on human tissue. For example, a dose equivalent of one SIEVERT (Sv) requires 1 Gy of beta or gamma radiation, but only 0.05 Gy of alpha radiation or 0.1 Gy of neutron radiation. Because the sievert is a large unit, radiation doses often are expressed in milliSIEVERTS (mSv). See TOTAL EFFECTIVE DOSE EQUIVALENT.

**duplicate, field**—Two samples of the same material, collected at the same location at the same time and under the same conditions, which are used to verify representativeness of the sampled material.

**duplicate, laboratory**—Two ALIQUANTS of a SAMPLE, which are prepared and analyzed separately as part of the same batch, used in the laboratory to measure the overall PRECISION of the sample measurement process, beginning with laboratory subsampling of a field SAMPLE.

**field duplicate**—See DUPLICATE, FIELD.

**graded approach**—A process of basing the level of management controls applied to an item or work on the intended use of the results and the degree of confidence needed in the quality of the results. The NRC follows a graded approach to project planning and QUALITY ASSURANCE because of the diversity of environmental data collection activities. This diversity in the type of project and the data to be collected impacts the content and extent of the detail to be presented in the project planning documents.

**gray (Gy)**—The International System of Units (SI) unit for absorbed radiation dose. One Gy is 1 joule of energy absorbed per kilogram of matter, equal to 100 RAD. See SIEVERT.

**laboratory control sample**—A standard material of known composition or an artificial SAMPLE (created by fortification of a clean material similar in nature to the sample), which is prepared and analyzed in the same manner as the sample. In an ideal situation, the result of an analysis of the laboratory control sample should be equivalent to (give 100 percent of) the TARGET ANALYTE concentration or activity known to be present in the fortified sample or standard material. The result normally is expressed as percent recovery. See also QUALITY CONTROL SAMPLE.

**laboratory duplicate**—See DUPLICATE, LABORATORY.

**matrix spike**—See SPIKE.

**measurement quality objective (MQO)**—The analytical data criteria of the DATA QUALITY OBJECTIVES, which are project- or program-specific and can be quantitative or qualitative. These analytical data criteria serve as measurement performance criteria or objectives of the analytical process. MARLAP (Ref. 20) refers to these performance objectives as MQOs. Examples of quantitative MQOs include statements of required analyte detectability and the UNCERTAINTY of the analytical protocol at a specified radionuclide concentration, such as the action level. Examples of qualitative MQOs include statements of the required specificity of the analytical protocol (e.g., the ability to analyze for the radionuclide of interest (or TARGET ANALYTE) given the presence of interferences).

**method uncertainty**—Reference to the predicted UNCERTAINTY of the result that would be measured if the method were applied to a hypothetical laboratory SAMPLE with a specified analyte concentration. Although individual measurement uncertainties will vary from one measured result to another, the REQUIRED METHOD UNCERTAINTY is a target value for the individual measurement uncertainties and is an estimate of uncertainty before the sample is actually measured. See also UNCERTAINTY and REQUIRED METHOD UNCERTAINTY.

**method validation**—The demonstration that the method selected for the analysis of a particular analyte in a given matrix is capable of providing analytical results to meet the project's MEASUREMENT QUALITY OBJECTIVES and any other criteria in the ANALYTICAL PROTOCOL SPECIFICATIONS. Compare with data and software VALIDATION.

**minimum detectable concentration**—The minimum detectable value of the analyte concentration in a sample. The smallest (true) value of the net state variable that gives a specified probability that the value of the response variable will exceed its critical value (i.e., that the material analyzed is not blank).

**minimum quantifiable concentration**—Minimum quantifiable value of the analyte concentration, defined as the smallest concentration of analyte whose presence in a laboratory SAMPLE ensures that the relative standard deviation of the measurement does not exceed a specified value, usually 10 percent.

**nonconformance**—a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate

**performance-based approach**—Definition of the analytical data needs and criteria of a project in terms of measurable goals during the planning phase of a project. In a performance-based approach, the project-specific data objectives that are determined during a DIRECTED PLANNING PROCESS serve as measurement performance criteria for selections and decisions regarding the conduct of the laboratory analyses. The project-specific analytical data objectives are also used for the initial, ongoing, and final evaluation of the laboratory's performance and the laboratory data. In method selection, a performance-based approach is the process wherein a validated method is selected based on a demonstrated capability to meet defined quality and laboratory performance criteria.

**performance evaluation (PE) program**—A laboratory's participation in an internal or external program of analyzing performance-testing samples appropriate for the analytes and matrices under consideration (i.e., PE program traceable to a national standards body, such as the National Institute of Standards and Technology (NIST) in the United States). Reference-material samples used to evaluate the performance of the laboratory are called performance-evaluation or performance-testing samples or materials. See CERTIFIED REFERENCE MATERIAL and STANDARD REFERENCE MATERIAL.

**performance indicator**—Instrument- or protocol-related parameter routinely monitored to assess the laboratory's estimate of controls such as chemical yield, instrument background, UNCERTAINTY, PRECISION, and BIAS. See BACKGROUND, INSTRUMENT.

**performance testing**—See PERFORMANCE EVALUATION PROGRAM.

**precision**—The closeness of agreement between independent test results obtained by applying the experimental procedure under stipulated conditions. Conversely, imprecision is the variation of the results in a set of REPLICATE measurements. Precision may be expressed as the standard deviation (IUPAC, Ref. 41).

**quality assurance (QA)**—An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected. Quality assurance includes QUALITY CONTROL.

**quality assurance project plan (QAPP)**—A formal document describing in detail the necessary QUALITY ASSURANCE, QUALITY CONTROL, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QA project plan describes policy, organization, and functional activities and the DATA QUALITY OBJECTIVES and measures necessary to achieve adequate data for use in selecting the appropriate remedy.

**quality control (QC)**—The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated objectives established by the project; operational techniques and activities that are used to fulfill objectives for quality. This system of activities and checks is used to ensure that measurement systems are maintained within prescribed limits, providing protection against out-of-control conditions and ensuring that the results are of acceptable quality.

**quality control (QC) sample**—An uncontaminated SAMPLE matrix spiked with known amounts of analytes from a source independent of the calibration standards.

**quality system**—A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing the work performed by an organization and for carrying out required QUALITY ASSURANCE and QUALITY CONTROL activities (ANSI/ASQC E4-1994, Ref. 21).

**readiness review**—The formal process of performing a written or verbal assessment of key attributes of a program or project measured against defined minimum criteria, standards, or quality metrics before initiation of activities under that project or program.

**record**—A retrievable document that furnishes objective evidence of the quality of products, services, or activities and that has been verified and authenticated as technically complete and correct.

**rem**—The common unit for the effective or equivalent dose of radiation received by a living organism, equal to the actual dose (in rads) multiplied by a factor representing the danger of the radiation. Rem is an abbreviation for roentgen equivalent man, meaning that it measures the biological effects of ionizing radiation in humans. One rem is equal to 0.01 Sv. See SIEVERT and DOSE EQUIVALENT.

**replicates**—Two or more ALIQUANTS of a homogenous SAMPLE whose independent measurements are used to determine the PRECISION of laboratory preparation and analytical procedures.

**reproducibility**—The closeness of the agreement between the results of measurements of the same parameter carried out under changed conditions of measurement. A valid statement of reproducibility depends upon specification of the conditions changed. The changed conditions may include principle of measurement, method of measurement, observer (or analyst), measuring instrument, reference standard, location, conditions of use, and time. Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results. Results are usually understood to be corrected results.

**required method uncertainty ($u_{MR}$)**—METHOD UNCERTAINTY at a specified concentration. This is a key MEASUREMENT QUALITY OBJECTIVE.

**sample**—(1) A portion of material selected from a larger quantity of material, or (2) a set of individual samples or measurements drawn from a population whose properties are studied to gain information about the entire population.

**sievert (Sv)**—The Système International (SI) unit for the effective dose of radiation received by a living organism. This unit represents the actual dose received (GRAYS in SI or rads in traditional units) times a factor that is larger for more dangerous forms of radiation. One Sv is 100 REM. Radiation doses are often measured in mSv. An effective dose of 1 Sv requires 1 GRAY of beta or gamma radiation, but only 0.05 Gy of alpha radiation or 0.1 Gy of neutron radiation.

**source, radioactive**—A quantity of material configured for radiation measurement.

**spike**—A known amount of TARGET ANALYTE added to the environmental sample to establish whether the method or procedure is appropriate for the analysis of the particular matrix and how the TARGET ANALYTE responds when the environmental sample is prepared and measured, thereby estimating the bias introduced by the sample matrix. Also termed MATRIX SPIKE.

**standard reference material**—A CERTIFIED REFERENCE MATERIAL issued by NIST in the United States. NIST certifies a standard reference material for specific chemical or physical properties and issues it with a certificate that reports the results of the characterization and indicates the intended use of the material.

**surveillance**—Continual or frequent monitoring and verification of the status of an activity and the analysis of records to ensure that specified requirements are being fulfilled. A surveillance is less extensive and more frequent than an AUDIT and concentrates on a single item or activity.

**survey**—A systematic evaluation and documentation of radiological measurements with a correctly calibrated instrument or instruments that meet the sensitivity required by the objective of the evaluation.

**target analyte**—A radionuclide on the list of radionuclides of interest or a radionuclide of concern for a project.

**test source**—The final radioanalytical processing product or matrix (e.g., precipitate, solution, filter) that is introduced into a measurement instrument. A test source is prepared from laboratory sample material for the purpose of determining its radioactive constituents. See CALIBRATION SOURCE, CHECK SOURCE, and SOURCE, RADIOACTIVE.

**total effective dose equivalent (TEDE)**—The sum of the effective dose equivalent (for external exposure) and the committed effective dose equivalent (for internal exposure), expressed in units of Sv or rem (MARSSIM, Ref. 28). See DOSE EQUIVALENT.

**uncertainty**—A parameter, usually associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurement of interest (Chapter 19 of MARLAP, Ref. 20).

**validation**—(1) *Data validation*, the evaluation of data to determine the presence or absence of an analyte and to establish the UNCERTAINTY of the measurement process for contaminants of concern. Data validation qualifies the usability of each datum (after interpreting the impacts of exceptions identified during data VERIFICATION) by comparing the data produced with the MEASUREMENT QUALITY OBJECTIVES and any other analytical process criteria contained in the ANALYTICAL PROTOCOL SPECIFICATIONS developed in the planning process. (2) *Software validation*, the confirmation by examination and provision of objective evidence that the particular criteria for a specific intended use are fulfilled. Validation for a system is the set of activities ensuring and gaining confidence that the system is able to accomplish its intended use, goals, and objectives (ISO/IEC 15288-2002, Ref. 42).

**verification**—(1) *Data verification*, a process that ensures that laboratory conditions and operations were compliant with the statement of work, sampling and analysis plan, and QUALITY ASSURANCE PROJECT PLAN and that identifies problems, if present, that should be investigated during data validation. Data verification compares the material delivered by the laboratory to these criteria (compliance) and checks for consistency and comparability of the data throughout the data package and for completeness of the results to ensure that all necessary documentation is available. (2) *Software verification*, the confirmation by examination and provision of objective evidence that specified criteria have been fulfilled. A set of activities compares a system life cycle product against the necessary characteristics for that product. The system life cycle products may include, but are not limited to, specified criteria, design description, and the system itself (ISO/IEC 15288-2002, Ref. 42).

# REFERENCES


1. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

2. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

3. 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

4. 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

5. 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

6. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[8]

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[8] All NRC regulations listed herein are available electronically through the Public Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; email PDR@nrc.gov.

[9] This regulation is available electronically through the U.S. Environmental Protection Agency's public Web site, at http://www.epa.gov/epacfr40/chapt-I.info/.

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[12] All regulatory guides listed herein were published by the U.S. Nuclear Regulatory Commission or its predecessor, the U.S. Atomic Energy Commission. Most are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/. Active guides may be purchased from the National Technical Information Service (NTIS). Details may be obtained by contacting NTIS at 5285 Port Royal Road, Springfield, Virginia 22161, online at http://www.ntis.gov, by telephone at (800) 553-NTIS (6847) or (703) 605-6000, or by fax to (703) 605-6900. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland; the PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4209, by fax at (301) 415-3548, and by email to PDR@nrc.gov.

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[16] Copies of all ANSI publications cited in this document may be purchased from the American National Standards Institute, 1819 L Street, NW, 6th floor, Washington, DC 20036. Purchase information is available through the ANSI Web site at http://webstore.ansi.org/ansidocstore/default.asp.

[17] Copies of all NIRMA Technical Guidance documents cited herein may be purchased from the Nuclear Information and Records Management Association, Inc., 10 Almas Road, Windham, NH; telephone (603) 432-6476; fax (603) 432-3024; see the NIRMA Web site at http://www.nirma.org/member/publications.htm.

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[20] Copies of this standard are available for purchase from the IEEE Web site at http://standards.ieee.org/db/status/index.shtml.

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